

RESTRICTION PRACTICE

**POLYNUCLEOTIDES
POLYPEPTIDES
AND FRAGMENTS**

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Official Gazette, 1192 O.G. 68 (Nov 19, 1996)

"Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121".

"Absent evidence to the contrary, each such nucleotide is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141".

"In some exceptional cases, the complex nature of the claimed material may necessitate that the reasonable number of sequences to be selected be less than 10".

"In other cases, applicants may petition pursuant to 37 CFR 1.181 for examination of additional nucleotide sequences by providing evidence that the different nucleotide sequences do not cover independent and distinct inventions".

Official Gazette, 1192 O.G. 68 (Nov 19, 1996)

Current Practice

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| <ul style="list-style-type: none">• Limited to expressed sequence tags (ESTs).• Polypeptides specifically not recited. One polypeptide per application.• Burden placed at up to ten (10) sequences. | <ul style="list-style-type: none">• All polynucleotides (DNA, RNA, and oligonucleotides).• No change to practice of one polypeptide per application.• Burden significantly increased. Number of sequences decreased, often to one (1) sequence and indistinct fragments thereof. |
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Linking Claims

- Restriction requirement is subject to nonallowance of the linking claim(s).
- Allowable linking claim(s) requires withdrawal of restriction as to any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s).
- Linking claims assessed on basis of 35 U.S.C. 101, 112, 102, and 103.

Linking Claims (MPEP §809.03)

Common types of linking claims which, if allowed, act to prevent restriction between inventions that can otherwise be shown to be divisible:

- Genus claims linking species claims
- Claims to the necessary process of making a product linking proper process and product claims
- Claims to "means" for practicing a process linking proper apparatus and process claims
- Claims to a product, linking claims to a process of making, and claims to a method of use of the product

Linking Claims

Common biotech example:

Claim 1. An isolated polynucleotide having antisense activity against SEQ ID NO:1.

Claim 2. The isolated polynucleotide of claim 1 selected from the group consisting of any one of SEQ ID NO: 2-125.

Linking Claims

- Claim 1 is a linking claim because it links each of inventions of SEQ ID NOs:2-125 together.
- Election of one of SEQ ID NOs:2-125 is required.
- Claim 1 examined with the elected invention.
- If claim 1 is allowable, all of inventions of SEQ ID NOs:2-125 become subject to examination.
- If claim 1 is not allowable, then only the elected invention is examined.

Linking Claims and Lack of Unity

- Consistent examination
- Consistent treatment of claims
- Consistent restriction practice

EnD

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